

SUMMARY OF COMMENTS & RESPONSES

Maine Comprehensive and Limited Laboratory Certification Rules

10-144 CMR Chapter 263

A public hearing was held at the Holiday Inn on Thursday, October 1, 2009 during a Board of Environmental Protection hearing. Both the Department of Environmental Protection and the Department of Health and Human Services attended, in order to address any comments. This joint rulemaking effort is required by 22 M.R.S.A. § 567(2).

The following individuals submitted comments within the prescribed periods. Individual comments were tabulated and summarized for analysis. Commenters providing both verbal and written comments, or only written comments, are listed as "written." Those comments received in both verbal and written form were counted as one comment.

ID Number	First Name	Last Name	Date	Representing	Format
1	Arthur	Clark	9/26/2009	USEPA Region 1	written
2	Richard	French	9/30/2009	MECDC HETL	written
3	James	Curlett	9/30/2009	MECDC HETL	written
4	Carlton	Gardner	10/06/2009	MECDC DWP	written

The following is a summary of the comments received, as well as a disposition by the Departments. The proposed change is deemed as: a) accepted as proposed, b) accepted with modifications per the commenters; or c) rejected. Strikethroughs indicate deletions and underlines indicate additions.

1. TABLE OF CONTENTS

Comment: Commenter #4 comments, "Fees section starts on page 77 not 76."

Disposition: The Department accepts the change as proposed and assures that the Table of Contents will accurately refer to the correct page numbers. The appropriate formatting changes have been made to the final rule.

2. Section 1: DEFINITIONS

Comment: Commenter #3 commented that the term "mobile laboratories" is not defined in the Rule.

Disposition: Finding no adverse impact from this comment, the Department accepts the change as proposed. The appropriate changes have been made to the final rule, as follows:

"NN. Mobile laboratory: "Mobile Laboratory" means (i) a portable enclosed structure within which testing or analysis of environmental samples occurs. (ii) Examples include trailers, vans and skid-mounted structures configured to house environmental testing equipment and personnel."

3. Section 3: PURPOSE AND SCOPE

A. Comment: Commenters #2, #3, and #4 commented that this section indicates these rules cover solid and chemical materials, but there is no reference to what methods will be offered for certification for solid and chemical materials in Section 5. Commenter #4 commented the need for the wording Resource Conservation Recovery Act.

Disposition: The Department concludes that the appropriate location for such inclusion is Section 5 (D). Finding no adverse impact from this comment, the Department accepts the change as proposed. The appropriate changes have been made to the final rule as follows:
Section 5:

D. Resource Conservation Recovery Act Program

- (1) Methods for the Resource Conservation Recovery Program test category are as provided under 40 CFR 261, and "Test Methods for Evaluation Solid Waste: Physical/Chemical Methods," Publication SW-846, as updated and published as final, EPA. The test methods are available on the internet at <http://www.epa.gov/epaoswer/hazwaste/test/main.htm>.
- (2) In the absence of an applicable federal regulation, alternative methods may be used for state-specific testing if the state agency administering the permit, program, or rule grants written approval citing the laboratory's name and the title, revision date, and revision number of the procedure receiving approval.
- (3) The laboratory must submit a copy of the approval of alternate methods to the certification officer, along with an application, as required under Section 4 (A) and fees as required under Section 21.
 - (a) The laboratory must validate standard methods used outside their published scope amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. This validation may be performed through a Demonstration of Capability.
 - (b) Modifications are allowed only if the modified method produces equivalent performance for the analyte(s) of interest, as determined by the certification officer, and the equivalent performance is documented.

B. Comment: Commenter #1 commented that Section 3 makes reference to nonpotable water and solid and chemical materials. This section is the only place where these terms are used. For example, Sec. 5.B discusses "wastewater program."

Disposition: Finding no adverse impact from this comment, the Department accepts the change as proposed. The appropriate changes have been made to the final rule as follows:

"This program will certify the following matrices: drinking water, wastewater, and Resource Conservation and Recovery Act aqueous, solid and chemical materials."

C. Comment: Commenter #4 stated that there are a few analytes that EPA has deemed not needed to be analyzed by a certified lab but that the Department may require a system to monitor for the analyte on a daily, weekly, or monthly basis, to insure the PWS is maintaining the proper chemical balance. Commenter #4 suggested adding language to the second paragraph of Section (3): "...involved in limited analysis required for system/treatment surveillance but deemed by EPA and the Maine Drinking Water Program as analytes not needed to be analyzed by a certified lab, pursuant to [citation]....."

Disposition: Finding no adverse impact from this comment, the Department accepts the change as proposed. The appropriate changes have been made to the final rule as follows:

"Drinking water laboratories of treatment plants involved in limited analysis required for system/treatment surveillance but deemed by EPA and the Department as analytes not required for analysis by a certified laboratory under 10-144 CMR 231, Section (7), approved by the Division of Environmental Health involved in limited analyses, namely

pH, residual free chlorine in its various forms, turbidity, and temperature do not need to be certified."

4. Section 4 CERTIFICATION PROCESS

A. Comment: Commenter #4 states, "Section 4 (A) (4) (a), should read "the form referred to in paragraph (C)" should read "paragraph (3)."

Disposition: Finding no adverse impact from this comment, the Department accepts the change as proposed. The appropriate changes have been made to the final rule as follows:

"(a) the form required under paragraph 3;"

B. Comment: Commenter #3 commented that Section 4 (I) (3), "Notification of clients going back 30 days is awfully burdensome."

Disposition: Finding no adverse impact from this comment, the Department accepts the change as proposed. The appropriate changes have been made to the final rule as follows:

"The effective date of suspension is the date that the laboratory receives the suspension notice from the certification officer. Upon receiving the notice, the laboratory must return to the client, or subcontract to another certified laboratory, samples for the field of testing of the suspension. During the suspension period, notification to clients whose samples are subcontracted or returned is required for all fields of testing for which the laboratory's certification has been suspended. The notification from the laboratory must be in writing. The laboratory must retain an electronic copy of each notification sent to the client for the review of the certification officer. The laboratory must submit a list of clients who received the notification, and one copy of the form letter used for the notification to the certification officer the time that the notification is sent to the client."

C. Comment: Commenter #3 commented that in Section 4 (J) (4), "Notification is overly burdensome."

Disposition: Finding no adverse impact from this comment, the Department accepts the change as proposed. The appropriate changes have been made to the final rule as follows:

"The effective date of revocation is the date that the laboratory receives the revocation notice from the certification officer via certified mail, return receipt requested. Upon receiving the notice, the laboratory must return to the client, or subcontract to another certified laboratory, samples for the field of testing of the revocation. Notification to the client is required for all fields of testing for which the laboratory's certification has been revoked. The notification from the laboratory must be in writing. The laboratory must retain an electronic copy of each notification sent to the client for the review of the certification officer. The laboratory must submit a list of clients who received the notification, and one copy of the form letter used for the notification to the certification officer at the time that the notification is sent to the client."

D. Comment: Commenter #4 comments, "Section 4 (F), the section on inspections, does not identify clearly the frequency of inspections. A two-year inspection appears to be required under Sections 4 (L) (3) (a) and 4 (F) (7)."

Disposition: Finding no adverse impact from this comment, the Department accepts the change as proposed. The appropriate changes have been made to the final rule as follows:

“(1) The certification officer may conduct inspections of certified laboratories or laboratories applying for certification. The certification officer must conduct a comprehensive on-site inspection of each laboratory prior to granting certification. In addition, an on-site inspection of each certified laboratory must be completed at least every two years.”

Furthermore, it was determined that the terms “assessment” and “inspection” were used to indicate onsite inspection. The term “assessment” was changed to “inspection” in the following sections:

Section 4 (F) (4):

“Additional on-site inspections, announced or unannounced, may be conducted to resolve problems indicated by deficiencies found during prior on-site inspections, or when there is a change of location, key personnel, equipment, or to resolve a complaint. If the deficiencies listed in a previous on-site inspection report are substantial or numerous, an additional on-site inspection may be conducted before a final decision for certification is made.

Section 4 J (3):

“(h) for out-of-state laboratories requiring an on-site inspection, failure to pay the inspection fee.”

5. Section 5 METHODS REQUIRED FOR CERTIFICATION

A. Comment: Commenter #4 comments, “Spacing of A and header appears off.”

Disposition: Finding no adverse impact from this comment, the Department accepts the change as proposed. The appropriate formatting changes have been made to the final rule.

B. Comment: Commenter #2 states for Section 5 (B) (1), “This citation restricts the methods for which certification is granted to just those listed in these two notices. It does NOT include additions or deletions made subsequently. Updates are planned for the wastewater methods. Revisions have been made to the drinking water methods since 2007. The citations should refer to the most recent version of the CFR Part 136 (wastewater). In addition, this is a citation for wastewater methods; it should not include drinking water methods.”

Disposition: The Department rejects this change, because it finds that the current language adequately addresses the current accepted methods for certification.

C. Comment: Commenter #2 states for Section 5 (B) (1), “In addition, this is a citation for wastewater methods; it should not include drinking water methods.”

Disposition: Finding no adverse impact from this comment, the Department accepts the change as proposed. The appropriate changes have been made to the final rule as follows:

“Methods for the Wastewater Program test category are as provided under the following sections: 40 CFR 136.3, Tables IC, IB and ID; 40 CFR 136.4; 40 CFR 136.5; 40 CFR 136, Appendices A, B, and C; Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act: Analysis and Sampling Procedures (also known as the “Methods Update Rule”), 72 Federal Register 47, March 12, 2007, 40 CFR 136; and Guidelines Establishing Test Procedures for the Analysis of Pollutants, Analytical Methods for Biological Pollutants in Wastewater and Sewage Sludge, 72 FR 57, March 26, 2007, 40 CFR 136 and 40 CFR 503, July 2007.”

D. Comment: Commenter #2 states for Section 5 (C) (1), “ I recommend citing “the most current versions of 40 CFR 141 and 143” in order to provide for additions to and deletions from these lists.”

Disposition: The Department rejects this change, because it finds that the current language adequately addresses the current accepted methods for certification.

E. Comment: Commenter #2 states for Section 5 (C) (1), “See the previous comment (referring to Section 5 B). This citation should be limited to drinking water methods; it should not include the wastewater methods” Commenter #3 states for this section, “Section 5.C.1: There are dual citations”.

Disposition: Finding no adverse impact from this comment, the Department accepts the change as proposed. The appropriate changes have been made to the final rule as follows:

“Methods for the Drinking Water Program test category are as provided under the following sections: 40 CFR §§ 141.23(k), 141.24(e), 141.24(f)(20), 141.27, 141.40(n)(11), 143.4(b); Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the National Primary Drinking Water Regulations: Analysis and Sampling Procedures (also known as the “Methods Update Rule”), 72 FR 47, March 12, 2007, 40 CFR 141, “Expedited Approval of Alternative Test Procedures of the Analysis of Contaminants Under the Safe Drinking Water Act; Analysis and Sampling Procedures”; 72 FR 107, June 3, 2008, 40 CFR §141; and “Expedited Approval of Alternative Test Procedures for the Analysis of Contaminants Under the Safe Drinking Water Act; Analysis and Sampling Procedures”, 74 FR 147, August 3, 2009.

6. Section 6 STANDARD OPERATING PROCEDURES

Comment: Commenter #4 comments, “Spacing of (A) and header appears off.”

Disposition: The Department believes that Commenter #4 reviewed an earlier version of the proposed rule changes. Upon review, the spacing was corrected in the most recent version.

7. Section 7 PROFICIENCY TESTING REQUIREMENTS

A. Comment: Commenter #2 states for Section 7 (E) (4), “a typo.” “For programs other than drinking water, a laboratory may use one PT sample to analyze and report results for multiple methods by the same technology, provided the sample is analyzed under analytical conditions which satisfy all technologies reported, and the most stringent method quality control requirements are fulfilled.”

Disposition: Finding no adverse impact from this comment, the Department accepts the change as proposed. The appropriate changes have been made to the final rule as follows:

“For programs other than drinking water, a laboratory may use one PT sample to analyze and report results for multiple methods by the same technology, provided the sample is analyzed under analytical conditions which satisfy all technologies reported, and the most stringent method quality control requirements are fulfilled.”

B. Comment: Commenter #2 states for Section 7 (J) (2) (a), “change a singular noun to a plural.” “none of the approved providers list the PT sample through published catalogs, web sites, or other widely distributed literature;

Disposition: After further review of this section, the Department determines a repeat of information in 7 (J) (1) (a) and (b) and 7(J) (2) (a) and (b). The appropriate changes have been made to the final rule as follows:

“If the certification officer determines that no approved provider has PT samples for a field of testing, the certification officer must request written documentation from the laboratory of quality control data, meeting the minimum requirements under Sections 1 to 21 to evaluate the capability of the laboratory to perform testing. “

The department has removed citations 7 (J) (2) (a) and (b) as it is duplicate information from 7(J) (1) (a) and (b).

C. Comment: Commenter #3 commented that this section, “Sub headers seem misplaced.” Commenter #4 commented, “Section 7, Spacing of A and header appears off and entire Section 7 appears to be mis-numbered.”

Disposition: The Department believes that Commenter #3 reviewed an earlier format of the proposed rule changes. Upon review, the spacing and numbering was corrected in the most recent version..

8. Section 8: APPROVED PROVIDERS OF PT SAMPLES

Comment: Commenter #3 commented that Section 8 (B) (6) (f)’s sub headers seem misplaced.

Disposition: Finding no adverse impact from this comment, the Department accepts the change as proposed. The appropriate formatting changes have been made to the final rule.

“(f) the following report information:

- (i.) analyte name for each analyte included in the sample;
- (ii.) method description;
- (iii.) laboratory value as reported;
- (iv.) assigned values and acceptance values reported to three significant figures, with the exception of tests requiring reports of presence or absence of the analyte;
- (v.) the acceptable/not acceptable status;
- (vi.) a "no evaluation" score for reported values containing alpha characters;
- (vii.) an indication of the amended results, for amended reports, including a brief description of the reason for the amendment; and
- (viii.) an indication of the length of the report presented by either "page X of Y" or the total number of pages with each page numbered consecutively;"

9. Section 11: STANDARDS, REAGENTS AND BACTERIOLOGICAL DATA

Comment: Commenter #2 recommends that Section 11(E) (2) references a bacteriological suitability test being performed annually as a requirement.

Disposition: The Department rejects this change, because it finds that the current language adequately addresses the issue of water quality for bacteriological use.

The reference for the bacteriological suitability test is from an EPA guidance manual, “*Manual for the Certification of Laboratories Analyzing Drinking Water Criteria and Procedures Quality Assurance*” EPA 815-R-05-004, January 2005 and was in out dated methods of *Standard Methods for the Examination of Water and Wastewater*.

Standard Methods for the Examination of Water and Wastewater, American Water Works Association, 21st Edition, 2005, a peer reviewed scientific resource, no longer reference the use of the bacteriological suitability test, but references “use tests” to determine the suitability of the water. These “use tests” are incorporated in this rule under Section 18 B (1), C and D.

10. Section 12: REQUIREMENTS FOR CALIBRATION OF SUPPORT EQUIPMENT

Comment: Commenter #4 states for Section 12 (C) (2), “ (.) after Units”

Disposition: The Department rejects this change, because it finds that the current language adequately addresses the frequency of calibration.

11. Section 14: REPORTING

A. Comment: Commenters #3 and #4 commented that this section does not support the electronic reporting of results to regulatory agencies.

Disposition: Finding no adverse impact from this comment, the Department accepts the change as proposed. The appropriate changes have been made to the final rule as follows:

“E. Electronic Reporting of Data to Regulatory Programs

- (1) If electronic reporting is required by the Program or these Rules, sample results must be reported in the electronic format acceptable to the Program.”

B. Comment: Commenter #4 comments, “Section 14 (D) does the word “record” refer to the laboratory quality records or the laboratory reports itself. This section should indicate both.”

Disposition: Finding no adverse impact from this comment, the Department accepts the change as proposed. The appropriate changes have been made to the final rule as follows:

“D. When the laboratory analyzes samples by a procedure other than as written, the laboratory records and reports must include:

- (1) the sample identification traceable to client;
- (2) the modification to the procedure;
- (3) the reason for the modification; and
- (4) the client's authorization or acknowledgment of the modification.”

12. Section 15: DOCUMENTS AND RECORDS

Comment: Commenter #4 states that Section 15 (B) (4) (a) – (j) appear to be mis-numbered and should be considered under a header of “C General Record Keeping Requirements.”

Disposition: Finding no adverse impact from this comment, the Department accepts the change as proposed. The appropriate changes have been made to the final rule as follows:

“(4) Procedures must be established to describe how changes in documents maintained in computerized systems are made and controlled.

(5) The record-keeping system must allow historical reconstruction of all laboratory activities that produced the analytical data. This requirement also applies to inter-laboratory transfers of samples or extracts and the data resulting from the analysis of the samples or extracts.

(6) Unless otherwise required by permit, program, or rule, all records must be retained for a minimum of five years after generation of the last entry in the record. All information required for the historical reconstruction of the data must be maintained by the laboratory. If records are retained only in electronic form, the hardware and software required for the retrieval of electronic records must be retained for the same time period as the records to be retrieved.

(7) The records must include the identity of personnel designated by the laboratory as responsible for the task performed, as described in the person's job description. The laboratory must retain records of the signatures and initials of designated personnel.

(8) All information relating to the laboratory facilities, equipment, analytical test methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification, must be documented.

(9) The record-keeping system must allow the retrieval of all working files and archived records for inspection and verification purposes, including, but not limited to, the systematic naming of electronic files.

(10) All records must be signed or initialed by personnel designated by the laboratory as responsible for the task performed. All changes must be clearly indicated in the records. The laboratory must have procedures for recording changes and identifying the personnel making the change.

(11) All observations used to calculate the final result must be recorded immediately. If the record is handwritten, the record must be legible and in permanent ink.

(12) Entries in records must not be obliterated by methods such as erasures, overwritten files, or markings. All corrections to records on paper must be made by one line marked through the error. The individual making the correction must sign or initial and date the handwritten or electronic correction.

(13) A laboratory must maintain a record-keeping system that includes procedures for protecting the integrity and security of the data.

(14) A laboratory must supply any documentation or data listed in Sections 1 to 19 within 7 calendar days of the date that the certification officer requests the information.”

13. Section 16: ORGANIZATION AND PERSONNEL

A. Comment: Commenter #4 commented that Section 16 (B) does not appear to allow for a part-time lab director, as is the case in Brewer.

Disposition: Finding no adverse impact from this comment, the Department accepts the change as proposed. The appropriate changes have been made to the final rule as follows:

“B. Laboratory Technical Director.

Each laboratory must appoint a laboratory technical director. The laboratory technical director is responsible for the technical and scientific oversight of all laboratory activities. The laboratory technical director must certify that personnel with appropriate education and technical background perform all tests for which the laboratory is certified. Each laboratory will be certified only after presentation of documentation to the department regarding education and work experience.”

B. Comment: Commenter #4 commented that Section 16 (B) (4) needs rewording.

Disposition: Finding no adverse impact from this comment, the Department accepts the change as proposed. The appropriate changes have been made to the final rule as follows:

“A valid treatment plant operator’s certificate/license can be substituted for the above qualifications for a laboratory technical director of a drinking water or wastewater treatment facility engaged in the analysis of bacteriology samples or chemistry, other than radiochemistry collected within the state. The certificate/license must be at least the classification for the drinking water or wastewater treatment facility where the laboratory is located.”

C. Comment: Commenter #2 states for Section 16 (B) (6) “change a singular verb to a plural.”

“An individual is not permitted to be laboratory technical director of more than one certified laboratory without authorization from the Department. Circumstances to be considered for authorization includes, but will not be limited to:”

Disposition: Finding no adverse impact from this comment, the Department accepts the change as proposed. The appropriate changes have been made to the final rule as follows:

“An individual is not permitted to be laboratory technical director of more than one certified laboratory without authorization from the Department. Circumstances to be considered for authorization include, but will not be limited to:”

D. Comment: Commenter #2 states for Section 16 C (1) “add clarifying word” “The QAO must review laboratory quality control data, conduct annual internal laboratory audits, and notify management of deficiencies found in the laboratory’s quality system. The QAO must be free from internal and external influences when evaluating data and conducting audits. The QAO must document training and/or experience in quality assurance/ quality control procedures and must have knowledge of the approved analytical methods and quality system requirements. The QAO must maintain the laboratory’s quality assurance documents up to date.”

Disposition: Finding no adverse impact from this comment, the Department added a clarifying word to the final rule as follows:

“The QAO must review laboratory quality control data, conduct annual internal laboratory audits, and notify management of deficiencies found in the laboratory’s quality system. The QAO must be free from internal and external influences when evaluating data and conducting audits. The QAO must have documented training and/or experience

in quality assurance/quality control procedures and must have knowledge of the approved analytical methods and quality system requirements. The QAO must maintain the laboratory's quality assurance documents up to date."

E. Comment: Commenter #2 states for Section 16 (D) (10) "change be to are" "The laboratory management must ensure that all personnel are responsible for complying with all quality assurance/quality control requirements that pertain to their organizational/technical function. Each technical staff member must have a combination of experience and education to adequately demonstrate a specific knowledge of their particular function and a general knowledge of laboratory operations, test methods, quality assurance/quality control procedures and records management."

Disposition: Finding no adverse impact from this comment, the Department accepts the change as proposed. The appropriate changes have been made to the final rule as follows:

"The laboratory management must ensure that all personnel are responsible for complying with all quality assurance/quality control requirements that pertain to their organizational/technical function. Each technical staff member must have a combination of experience and education to adequately demonstrate a specific knowledge of their particular function and a general knowledge of laboratory operations, test methods, quality assurance/quality control procedures and records management."

14. Section 20 (now Section 21): FEES

Comment: Commenter #2 commented that this section does not reference fees for solid and chemical materials. Commenter # 3 recommended removing the term "Volatile" from Wastewater and Drinking Water Fee Table, and there is no mention of fees for RCRA testing.

Comment: In Section 21 (A)(2)(b), Commenter #3 suggested a clarification or removal of sample prep fees. There is quite a discrepancy in the various programs and matrices with the term "sample preparation techniques." For example, the extraction procedures are included as part of the determinative method in Drinking and Waste Waters, in the Solid Waste Methods they are both included and also in as stand alone preparation methods conceivably both extraction and cleanup techniques. This would then discriminate against labs doing solids. Commenter #4 commented: "Fees for volatile organics, but not for semi-volatile organics?"

Disposition: Finding no adverse impact from this comment, the Department accepts the change as proposed. The appropriate changes have been made, and the final rule appears as follows:

"SECTION 21: FEES

A. The appropriate fee in accordance with the following schedule must accompany an application for accreditation, renewal of accreditation, or addition of fields of accreditation.

(1) The total annual certification fee includes the base fee, test methods fees, and, when applicable, the on-site inspection fee.

(2) The annual certification fees include the following:

1. base certification fee, \$1,250;
2. test category certification fees:

TEST METHOD**CERTIFICATION FEE**

Wastewater program bacteriology	\$50 per method
Drinking water program bacteriology	\$50 per method
Wastewater program inorganic chemistry	\$50 per method
Drinking water program inorganic chemistry	\$50 per method
Resource conservation recovery program inorganic chemistry	\$50 per method
Wastewater program metals	\$100 per method
Drinking water program metals	\$100 per method
Resource conservation recovery program metals	\$100 per method
Wastewater program organic compounds	\$125 per method
Drinking water program organic compounds	\$125 per method
Resource conservation recovery program organic compounds	\$125 per method
Oil Program or Leaking Underground Storage Tanks (LUST) Program organic compounds	\$125 per method
Drinking water program radiochemistry	\$125 per method

(3) The total biennial certification fee includes the base fee, the test method fees, and, when applicable, the on-site inspection fee.

(4) The biennial certification fees include the following:

- a) base certification fee of \$1,250;
- b) test category certification fees

TEST METHOD	CERTIFICATION FEE
Wastewater program bacteriology	\$100 per method
Drinking water program bacteriology	\$100 per method
Wastewater program inorganic chemistry	\$100 per method
Drinking water program inorganic chemistry	\$100 per method
Resource conservation recovery program inorganic chemistry	\$100 per method
Wastewater program metals	\$200 per method
Drinking water program metals	\$200 per method
Resource conservation recovery program metals	\$200 per method
Wastewater program organic compounds	\$250 per method
Drinking water program organic compounds	\$250 per method
Oil Program or Leaking Underground Storage Tanks (LUST) Program organic compounds	\$250 per method
Resource conservation recovery program organic compounds	\$250 per method
Drinking water program radiochemistry	\$250 per method

(5) The limited laboratory certification fee is \$650 for biennial certification.

(6) The environmental lead program fee is \$600 for biennial certification.

(7) The Department will assess a fee for an on-site inspection to out-of-state laboratories. This fee will be based on the established hourly rate of the

laboratory certification officer inclusive of preparation time, travel time and inspection time, as well as the travel expenses (travel, meals, lodging and other associated travel expenses) incurred. The minimum fee assessed will be \$1,500 and the maximum fee will be \$3,750.

- (8) A change fee will be assessed if a laboratory requests additional methods at any time other than when applying for or renewing its certification.
- (9) Refunds or credits will not be made for analytes or methods requested, but not approved.
- (10) Certification of a laboratory will not be awarded until all fees are paid.”

15. General Formatting

A. Comment: Commenter #4 stated that the Rules reference the terms “paragraphs” and “sub-sections” throughout the document, and Commenter #4 felt that in places, the terms appear to be used interchangeably, and suggested a review for standardization.

Disposition: The Department reviewed the entire document for consistency in using the terms. When unnumbered paragraphs exist in a particular section, the Department referred to it as a paragraph, but if the place is within a subsection, then the Department referred to the specific sub-section. The appropriate formatting changes were completed for the final rule.

B. Comment: Commenter #4 stated that the rules reference numbers inconsistently throughout the rule in both numeric characters and spelled out.

Disposition: The Department chose to refer to specific numerals throughout the rules and made the appropriate formatting changes to the final rule.